REMARKS/ARGUMENTS

Claims 2-6, 8-24 are pending in the present application, with claims 20 and 21 being independent. Claims 11, 12, 17, 18, and 20 have been amended.

New claims 21-24 have been added. These claims are similar to claims 20 and 2-4, respectively, but are intended to be construed without resort to 35 U.S.C. § 112, sixth paragraph.

Rejections Under 35 U.S.C. § 112

Claims 12-19 are rejected under 35 U.S.C. § 112, first paragraph, as lacking written description support in the specification. In particular, with respect to claim 12, the Examiner takes issue with the use of the term "might" in the phrase: "the proximal flange or proximal lateral tabs that the body of the syringe might have." Claim 12 has been amended to delete the term "might." Withdrawal of this rejection is therefore requested.

Claims 2-6 and 8-20 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Specifically, the Examiner deems certain claim terms to lack antecedent basis.

The M.P.E.P. provides the following guidance regarding indefiniteness of claims for lack of antecedent basis:

> A claim is indefinite when it contains words or phrases whose meaning is unclear. The lack of clarity could arise where a claim refers to "said lever" or "the lever," where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference. . . . Obviously, however, the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. *Ex parte Porter*, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992) ("controlled stream of fluid" provided reasonable antecedent basis for "the controlled fluid").

M.P.E.P. § 2173.05(e)(emphasis added). Thus, antecedent basis problems may arise for claim terms introduced by definite articles, e.g., "said lever" or "the lever," when there is no earlier recitation of the term, e.g., "a lever," because it may be unclear which particular lever is being referenced by the later-occurring phrase. However, explicit antecedent basis is not required if the scope of the claim "would be readily ascertainable by those skilled in the art."

With respect to claims 2, 4, 5, 9, 12, 14, 15, 17, and 20, the Office Action states that certain terms in these claims lack antecedent basis because "none of the claims positively recite the device comprising" the term in question (Office Action at pages 2-3). However, the Examiner has not cited any patent law, rule, or USPTO practice requiring that all terms introduced with "said" or "the" refer back only to terms that are "positively recited."

Under USPTO practice, as discussed in the M.P.E.P. section cited above, a term has sufficient antecedent basis when there is a recitation of the term earlier in the claim or in a preceding claim using an indefinite article, e.g., "a lever." Such earlier recitation may be, for example, in the preamble of the claim in question or a preceding claim, as in claim 20, which recites: "[a]n accessory for a syringe, the syringe having a syringe body with a proximal end having a flange and a distal end for supporting a needle at the distal end by way of an adapter." This preamble provides antecedent basis for the terms "flange," "syringe," and "adapter," even though they constitute the environment in which the invention is to be used, rather than elements of the invention itself.

Under the Examiner's view of antecedent basis, it would be impossible to refer back to a term in the preamble of a claim defining the environment of an invention, because that apparently would not be considered to be a "positive recitation." Thus, Applicants would have to claim the environment in which the invention is to be used as part of the invention itself. This position is clearly incorrect as a matter of law.

Regardless, the claims in question are deemed to be sufficiently definite under 35 U.S.C. § 112, second paragraph, because they do not contain "words or phrases whose meaning is unclear," and the scope of these claims would be "reasonably ascertainable by those skilled in the art."

Accordingly, the rejections of claims 2, 4, 5, 9, 12, 14, 15, 17, and 20 under 35 U.S.C. § 112, second paragraph, are respectfully traversed.

Claims 9, 11, 12, and 17 have been amended to address the antecedent basis concerns raised in paragraphs 2-10 of the Office Action. Regarding claim 13, there is antecedent basis for the phrase "the proximal flange or lateral tabs" in claim 12, and Applicants note that the term "might" has been deleted from claim 12. Withdrawal of these rejections is therefore requested.

Discussion of Disclosed Embodiments

The following descriptive details are based on the specification. They are provided only for the convenience of the Examiner as part of the discussion presented herein, and are not intended to argue limitations, which are unclaimed.

The present application relates to an accessory configured to hold a syringe in a manner that prevents the needle from becoming detached or unscrewed during use. A syringe, as shown for example in Figure 2, has a needle (7) attached to a syringe body (5) using an adapter (8). The needle (7) may be bent, as is typically used in ophthalmic surgery. The adapter (8) may be conical in shape and may be ribbed. The adapter (8) may be attached to the syringe body (5) using a nut (11) of the "Luer-lock" type. (Specification at page 5, lines 11-26).

When injections are performed using a syringe of this type, longitudinal stress may be generated at the needle, particularly in the case of viscous fluids. There is a risk that such stress may cause the needle to separate from the syringe body during injection. The use of a Luer-lock

arrangement can reduce this risk, but there is still the risk that the adapter might become unscrewed during injection. Even partial unscrewing of the adapter can be harmful, especially if the needle is bent or curved. (Specification at page 1, lines 5-16).

The present application seeks to prevent unscrewing and/or detachment of the adapter and needle by providing an accessory (1) in which the syringe can be installed prior to use. The accessory (1), as shown in Figures 1 and 2, has a body (15) with two regions (16 and 17) joined by an elastic zone (18). (Specification at page 5, lines 27-34).

The distal portion (16) of the body (15) has a transverse wall (20) having a hole (22) into which the needle (7) is inserted. The wall (20) is shaped to receive a conically-shaped adapter (8) that attaches the needle (7) to the syringe body (5). The hole (22) may have a slot (25) to allow the needle (7) to be engaged in the accessory (1) without having to insert the needle (7) through the hole (22), which may be difficult to do in practice.

The wall (20) may have a radial arrangement of teeth (26) projecting from its inner surface to engage with the ribs of the adapter (8) and thereby prevent rotation of the adapter (8) during injection. (Specification at page 5, line 35 – page 6, line 11). The proximal portion (17) of the accessory body (15) may have an arrangement of transverse walls (30 and 31) configured to receive the flange (10) of the syringe to help hold the syringe in place within the accessory (1). (Specification at page 6, lines 12-32).

Summary of Cited References

Stine, as shown in Figure 1, relates to an aspiration syringe holder having a body portion for receiving a syringe. A handle is provided at a rear portion of the holder, and a trigger is mounted at the front end of the holder in a longitudinal sliding engagement with the holder body. (Stine at

Abstract). As shown in Figure 14, the holder may have a pair of rails (312a and 312b) connecting a forward ring (315) to a rear portion (317), which has a groove (318) that engages with the flange of the syringe. The trigger (325) is mounted so that it slides on the rails to pull back the plunger of the syringe.

Nolan relates to a syringe adapter that allows a drive member of an injector to communicate force to the plunger of the syringe without a connecting relationship between the drive member and the plunger. As shown in Figures 4A-4I, the adapter (400) has a rearward portion (420) with flat walls that accommodates the syringe flange (230). The adapter has a forward portion (430) that accommodates the syringe barrel (210). The forward portion (430) includes a "radially inward extending abutment shoulder" (450) that abuts the cone-shaped transition region (240) of the syringe (200).

Rejections Under 35 U.S.C. § 103

Claims 2-6 and 8-20 stand rejected under 35 U.S.C. § 103(a) as being obvious over Stine (U.S. 4.594,073) in view of Nolan (U.S. 6,743,205).

Claim 20 recites, *inter alia*, an accessory body having a longitudinal axis, a distal end and a proximal end, the accessory body having an elastic zone forming an integral part of the accessory body and being arranged between the distal end and the proximal end coupling the distal end and the proximal end, the elastic zone configured to expand elastically in the longitudinal direction of the accessory from a first, rest position, to a second position where a distance between the distal and proximal ends is increased.

The cited references, taken alone or in combination, do not disclose an accessory body having an elastic zone formed as an integral part of the accessory body, as recited in claim 20. The

syringe holder disclosed in Stine is formed of injection molded plastic mixed with fiberglass (see Stine at col. 4, lines 3-9). The syringe holder disclosed in Nolan is likewise formed of a rigid material, with certain portions, such as a ridge portion (154), being formed of elastomeric materials.

It follows, then, that the combination of the cited references also does not disclose an elastic zone configured to expand elastically in the longitudinal direction of the accessory from a first, rest position, to a second position where a distance between the distal and proximal ends is increased, as further recited in claim 20.

During examination, the USPTO "determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.'" M.P.E.P. § 2111 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005)).

The Office Action cites Stine as purportedly disclosing "an accessory body having an elastic zone." (Office Action at page 4). However, the Examiner considers the space between the forward ring (315) and the groove (318) that engages with the flange of the syringe, as corresponding to the claimed elastic zone. This interpretation is not consistent with the specification as it would be interpreted by one of ordinary skill in the art, because the elastic zone is clearly described as being part of the accessory body itself. Nevertheless, claim 20 has been amended to recite that the elastic zone is "formed as an integral part of the accessory body" to foreclose this overly broad interpretation.

Furthermore, the Examiner interprets the term "elastic" to mean "being able to adjust readily to different conditions." Based on this definition, the Examiner finds Stine to disclose the claimed elastic zone, because "Stine teaches the device being easily adjustable to accommodate syringes of

various lengths." However, the Examiner has not cited any source for this definition of "elastic" and has not even asserted that it is the meaning that one of ordinary skill in the art would give to that term.

The device disclosed in Stine, as noted above, has a trigger (325) that slides on guide rails (312a and 312b). This structure is not disclosed as being elastic in any way and would not be understood by one of ordinary skill in the art to be elastic. As noted above, the structure is formed of rigid injection-molded plastic. Nevertheless, claim 20 has been amended to recite "the elastic zone being configured to expand elastically in the longitudinal direction of the accessory" to emphasize that the structure undergoes an elastic expansion, as opposed to a mere sliding of separate rigid parts.

In view of the above, claim 20 is deemed to be patentable over the combination of Stine and Nolan.

New claim 21 recites features similar to claim 20 (but without "means-plus-function" limitations) and is therefore also deemed to be allowable over the cited references.

Dependent claims 2-4 recite features relating to preventing the syringe adapter from rotating. Claim 2 recites: "further comprising at least one means for preventing the adapter from rotating with respect to the accessory body." Claim 3 recites: "wherein said rotation-preventing means comprises at least one tooth projecting from the first holding means." Claim 4 recites: "wherein the wall of the first holding means defines a hole for receiving the needle therein and wherein said at least one tooth comprises several teeth arranged around the hole."

The Office Action states that "Nolan, Jr. et al. disclose in Figures 4, 8, and 9 that it is known to incorporate teeth surrounding an opening hole." (Office Action at page 4). However, Nolan does not disclose teeth, or any similar structure, surrounding an opening hole to prevent rotation of the

syringe adapter. Moreover, Nolan does not even recognize the importance of preventing the syringe adapter from rotating during injection. Stine also fails to disclose these features.

Accordingly, it is respectfully submitted that *prima facie* obviousness has not been established with respect to claims 2-4. An indication of the allowability of these claims is therefore requested.

Claims 2-6, 8-19, and 22-24 are each dependent from one of independent claims 20 or 21 and are therefore believed patentable for the same reasons. Since each dependent claim is also deemed to define an additional aspect of the invention, however, the individual consideration or reconsideration of the patentability of each on its own merits is requested.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application.

Please charge our Deposit Account No. 03-2412 in the amount of $104 for two claims in excess of twenty.

It is believed that no additional fees or charges are required at this time in connection with the present application. However, if any additional fees or charges are required at this time, they may be charged to our Deposit Account No. 03-2412.

Respectfully submitted,
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